

Serial No. 09/973,265
Filing Date: October 9, 2001
Rampal et al.
Page 2

Amendments to the Claims

Claims:

1. (Currently Amended) A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising a mixture of omeprazole and a pharmaceutically acceptable carrier, the carrier comprising at least one water insoluble polymer and at least one water soluble polymer, wherein the water soluble polymer is polyvinyl pyrrolidone or vinylpyrrolidone-vinyl acetate copolymer.
2. (Previously Amended) The composition of claim 1 wherein the water insoluble polymer has vinylpyrrolidone units.
3. (Previously Amended) The composition of claim 2 wherein the water insoluble polymer is cross-linked polyvinylpyrrolidone.
4. (Cancelled)
5. (Cancelled)
6. (Currently Amended) The composition of claim 1, ~~[A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising a mixture of omeprazole and a pharmaceutically acceptable carrier, the carrier comprising at least one water insoluble polymer,~~] wherein the carrier comprises at least about 40% by weight of omeprazole.

Serial No. 09/973,265
Filing Date: October 9, 2001
Rampal et al.
Page 3

7. (Currently Amended) A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising a mixture of omeprazole and a pharmaceutically acceptable carrier, the carrier comprising at least one water insoluble polymer and the mixture further comprises other pharmaceutically acceptable excipients, wherein the mixture further comprises lubricants, plasticizers, fillers and binders.
8. (Withdrawn) The composition of claim 7 wherein the mixture further comprises a fatty acid glyceride.
9. (Cancelled)
10. (Currently Amended) The composition of claim [9] 7 wherein the lubricants are selected from the group consisting of talc, magnesium stearate, calcium stearate, polyethylene glycol, sodium stearyl fumarate, and mixtures thereof.
11. (Currently Amended) The composition of claim [9] 7 wherein the plasticizers are selected from the group consisting of triethyl citrate, polyethylene glycol, and mixtures thereof.
12. (Currently Amended) The composition of claim [9] 7 wherein the binder is selected from the group consisting of polyvinyl pyrrolidone, starch, low viscosity grade hydroxypropyl methylcellulose, hydroxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and mixtures thereof.
13. (Currently Amended) The composition of claim [9] 7 wherein the fillers are selected from the group consisting of lactose, sucrose, mannitol, and microcrystalline cellulose.

Serial No. 09/973,265
Filing Date: October 9, 2001
Rampal et al.
Page 4

14. (Currently Amended) The composition of claim 1, [A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising a mixture of omeprazole and a pharmaceutically acceptable carrier, the carrier comprising at least one water insoluble polymer and] the [pharmaceutical] composition being in the form of a capsule, the mixture being contained within a capsule shell made from and/or coated with an enteric material.
15. (Withdrawn) The composition of claim 14 wherein the mixture contained within the capsule shell is in the form of a powder blend.
16. (Currently Amended) The composition of claim 14 wherein the mixture contained within the capsule shell is in the form of granules.
17. (Cancelled)
18. (Cancelled)
19. (Cancelled)
20. (Original) The composition of claim 1 in the form of a tablet.
21. (Previously Amended) The composition of claim 1 in the form of a bead or a pellet, wherein the mixture is coated on a neutral core.
22. (Previously Amended) The composition of claim 21, wherein the neutral core has previously been coated with a coating mixture before coating with the mixture of claim 1.

Serial No. 09/973,265

Filing Date: October 9, 2001

Rampal et al.

Page 5

23. (Currently Amended) A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising a mixture of omeprazole and a pharmaceutically acceptable carrier, the carrier comprising at least one water insoluble polymer and at least one water soluble polymer, the water soluble polymer being polyvinyl pyrrolidone or vinylpyrrolidone-vinyl acetate copolymer, the composition being in the form of a bead or a pellet, wherein the mixture is coated on a neutral core and the neutral core has previously been coated with a coating mixture before coating with the mixture of omeprazole and pharmaceutically acceptable carrier, wherein **[said]** the coating mixture contains water soluble or water insoluble polymers optionally with other pharmaceutically acceptable excipients.
24. (Currently Amended) A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising a mixture of omeprazole and a pharmaceutically acceptable carrier, the carrier comprising at least one water insoluble polymer and at least one water soluble polymer, wherein the water soluble polymer is polyvinyl pyrrolidone or vinylpyrrolidone-vinyl acetate copolymer, the composition is in the form of a bead or a pellet, and the mixture is coated on a neutral core, [The composition of claim 21] wherein the neutral core coated with **[said]** the mixture is further coated with one or more intermediate layers, and an outer enteric layer.
25. (Currently Amended) The composition of claim 24 wherein **[an]** the enteric layer has an enteric polymer.

Serial No. 09/973,265
Filing Date: October 9, 2001
Rampal et al.
Page 6

26. (Currently Amended) The composition of claim 24 wherein the one or more intermediate layers ~~[layer(s) may]~~ contain water soluble or water insoluble polymers, optionally with other pharmaceutically acceptable excipients.
27. (Currently Amended) A pharmaceutical composition which is stable and suitable for oral administration to a patient, comprising (a) a neutral core coated with a mixture of omeprazole and a pharmaceutically acceptable carrier, said carrier comprising at least one water insoluble polymer, (b) one or more intermediate layer(s), optionally comprising water soluble or insoluble polymers, and (c) an enteric coated layer, wherein the composition is in the form of a bead or a pellet and the beads or pellets are compressed into tablets or filled in a capsule.
28. (Cancelled)
29. (Cancelled)
30. (Withdrawn) A process for preparing a stable pharmaceutical composition which is suitable for oral administration, comprising mixing omeprazole together with a pharmaceutically acceptable carrier, said carrier comprising at least one water insoluble polymer.
31. (Withdrawn) The process of claim 30 wherein said polymer has vinylpyrrolidone units.
32. (Withdrawn) The process of claim 31 wherein said polymer is cross-linked polyvinylpyrrolidone.

Serial No. 09/973,265
Filing Date: October 9, 2001
Rampal et al.
Page 7

33. (Withdrawn) The process of claim 30 wherein said carrier further comprises water soluble polymers.
34. (Withdrawn) The process of claim 33 wherein said polymer is polyvinyl pyrrolidone or vinylpyrrolidone-vinylacetate copolymer.
35. (Withdrawn) The process of claim 30 further comprising mixing at least one pharmaceutically acceptable excipient into said mixture.
36. (Withdrawn) The process of claim 35 wherein said pharmaceutically acceptable excipient is a fatty acid glyceride.
37. (Withdrawn) The process of claim 35 wherein said pharmaceutically acceptable excipient is a lubricant, plasticizer, filler, or a binder.
38. (Withdrawn) The process of claim 30 further comprising filling said mixture in the form of a powder blend into a capsule made from an enteric material.
39. (Withdrawn) The process of claim 30 further comprising coating a capsule shell with an enteric material, and filling said mixture in the form of a powder blend into said capsule shell.
40. (Withdrawn) The process of claim 30 further comprising granulating said mixture to produce granules, and filling said granules into a capsule shell made from an enteric material.

Serial No. 09/973,265
Filing Date: October 9, 2001
Rampal et al.
Page 8

41. (Withdrawn) The process of claim 30 further comprising granulating said mixture so as to form granules, coating a capsule shell with an enteric material, and filling said granules into said capsule shell.
42. (Withdrawn) The process of claim 30 further comprising compressing said mixture into tablets.
43. (Withdrawn) The process of claim 30 comprising coating said mixture on a neutral core.
44. (Withdrawn) The process of claim 31 wherein said neutral core has previously been coated before coating of said mixture.
45. (Withdrawn) The process of claim 30 wherein neutral core coated with said mixture is further coated with one or more intermediate layers, and an outer enteric layer.
46. (Withdrawn) The process of claim 30 further comprising forming beads or pellets.
47. (Withdrawn) The process of claim 46 further comprising compressing beads or pellets into tablets or filling said beads or pellets in a capsule.